Attachment 1
Specific Comments on EPA's Proposed Plan for the VBI70 Site
The Agency for Toxic Substances and Disease Registry
July 19, 2002

Arsenic Clean-up Level

About 390 properties will have average arsenic levels between 47 to 127 ppm, and the preferred alternative (i.e., #4) will allow arsenic exposure at these properties until a child is found to have elevated arsenic levels in urine.

At an average arsenic level of 127 ppm, some parts of the yard could contain arsenic levels as high as 800 ppm. Should a preschool child with soil-pica behavior eat 5,000 milligrams (mg) dirt from this part of the yard, the estimated dose is 0.17 mg/kg/day (800 ppm x 5000 mg/day x 0.42 x E-6 / 10 kg). This estimated dose of 0.17 mg/kg/day is well above the 0.05 mg/kg/day dose known to cause nausea, vomiting, diarrhea, headache, facial swelling, fatigue, chills, and sore throats in humans (Mizuta 1956, Armstrong 1984, Franzblau and Lilis 1989, ATSDR 2000).

A serious public health threat remains at these properties because a 1-time exposure could cause harmful effects in children. The approach of testing children to find children with elevated urine arsenic will allow serious arsenic exposure to occur before EPA will take action. It should also be pointed out that a testing program as proposed in the alternative #4 cannot prove that a child's environment is safe.

As we mentioned in ATSDR's Public Health Assessment for the VBI70 site (released March 5, 2002), some uncertainty exists in deciding if harmful effects might occur in children and adults because of elevated soil arsenic levels and in children because of elevated soil lead levels at the VBI70 site. Therefore, ATSDR proposes that lower clean-up levels be selected and that the clean-up levels should be somewhere between the levels proposed in alternative #4 and alternative #5.

Arsenic and Cancer

ATSDR is concerned that the proposed 128 ppm arsenic clean-up level will not sufficiently reduce the risk of cancer from long-term exposure. This concern arises from some of the input parameters used to estimate cancer risk and include the following points:

1. The relative bioavailability of arsenic in soil may not be accurately assessed. In conducting the swine study for the VBI70 site, the control pigs were lost for 1 of the 2 dosing periods resulting in having to use the control pigs from the 2nd dosing period of the study to estimate bioavailability for the entire study.
2. Only 5 soil samples were used to assess the variation in arsenic bioavailability for the entire site.
3. The use of a 95% upper confidence limit to assess variation may not accurately account for all the variation that exists in arsenic bioavailability.

4. It is important to realize that the swine study protocol has never been critically reviewed by an expert panel.
5. EPA used an exposure period of 30 years to estimate cancer risk. However, a significant portion of adults live in the neighborhood for more than 30 years.
6. EPA based a portion of someone's exposure to arsenic by assuming that approximately 50% of "soil" exposure comes from indoor dust. This assumption is based on one study.
7. EPA used a whole-house indoor sample to estimate someone's exposure to arsenic from indoor dust. Information is not available to show that a whole-house indoor dust sample (versus discrete indoor dust samples from various parts of the house) is the best method to use to estimate people's exposure to contaminants in indoor dust. For example, at the Eureka Mill site, EPA used three indoor discrete dust samples to estimate a child's exposure to lead in dust.

Arsenic Clean-up Levels at Other Sites

The 128 ppm clean-up level for arsenic at the VBI70 site, which is based on cancer risk, appears inconsistent with the significantly lower clean-up levels for arsenic at other sites in EPA Region VIII, which are also based on cancer risk. For example, at the Eureka Mills Site in Utah, EPA Region VIII developed a clean-up level of 77 ppm for arsenic, and at the ASARCO Globeville Site in Denver, a clean-up level of 70 ppm was established. The attached Table 1 shows arsenic clean-up levels at other sites in Region VIII.

Table 1				
EPA Region	EPA ID	Site Name	Arsenic Clean-up Level Surface Soil ppm	Land Use
VIII	CO0002259588	Vasquez Boulevard and I-70 (VBI70)	128 ppm	Residential
VIII	COD980717953	Sand Creek Industrial	12.7 ppm	Residential
VIII	COD007063530	Globeville ASARCO, Inc.	70 ppm	Residential
VIII	MTD093291656	Anaconda Co. Smelter (OU1)	73 ppm	Residential
VIII	MTD093291656	Anaconda Co. Smelter (OU 4, 7, 11)	250, 500, 1,000 and 2,500 ppm	Residential and Industrial
VIII	UT9210020922	Ogden Defense Depot	35 ppm	Residential
VIII	UT0002240158	Eureka Mills	77 ppm	Residential
VIII	UTD980718670	Portland Cement Kiln	70 ppm	Residential

Lead Clean-up Levels

At the Eureka Mills Site in Utah, EPA developed a remedial action level of 231 ppm based on the IEUBK lead model. A comparison of the IEUBK parameters for the Eureka Mills Site and the VBI70 site follow:

Table 2. Comparison of IEUBK Parameters for Eureka Mills and VBI70

	VBI70	*Eureka Mills*
Lead clean-up level	540 ppm	231 ppm
Geometric Standard Deviation (GSD)	1.2	1.4
Dietary intake	1.82 to 2.02 μg/day	3.87 to 4.9 μg/day

One of the reasons the clean-up levels vary is the difference in the Geometric Standard Deviation (GSD) value used in the IEUBK model. At the VBI70 site, a GSD of 1.2 was used to develop the remedial action level of 540 ppm while a higher GSD level (i.e., 1.4) was used at the Eureka Mills Site. Using a lower GSD level is one of the main reasons that the clean-up levels are vastly different.

It is interesting to note that the relative bioavailability (RBA) of lead for the VBI70 site was found to be 84% based on a site-specific pig study and the RBA for the Eureka Mill site was estimated to be 70% based on a comparison to other pig studies. Even though the lead at the VBI70 site has a higher bioavailability, the ultimate clean-up number at VBI70 was not lower but higher than the Eureka Mills Site.

It should be pointed out that recent food basket surveys from the FDA show that lead intake in children's diet has decreased since the model was developed. The default dietary lead intake for the model should probably be adjusted in light of this new information. Adjusting the dietary intake to a lower level was done at both the VBI70 site and the Eureka Mills Site. What is interesting to note is that the adjusted dietary intakes differ even though the baseline risk assessments for both sites were released within a month of each other (i.e., August 2001 for the VBI70 site and September 2001 for the Eureka Mills Site). It is important to realize that using a lower dietary intake for lead for the VBI70 site presumably sets the baseline blood lead levels lower, which means that it takes a higher lead intake to exceed the 10 μg/dL level of concern. In essence, this increases the clean-up level for lead in soil. Whether or not this is a significant increase can only be determined by comparing the influence of the dietary intake level on the resulting clean-up level.

Geometric Standard Deviation

In using the IEUBK model to derive the lead action level of 540 ppm for the VBI70 site, EPA adjusted the GSD for blood lead distribution from the default value of 1.6 to several lower GSDs; and, used the lowest GSD (i.e., 1.2) to develop the action level of 540 ppm. To ATSDR's knowledge, this is the lowest GSD that has been used at a hazardous waste site. EPA's guidance on selecting the GSD for the IEUBK model states the following:

"The Guidance Manual describes the selection of the GSD value of 1.6, based on calculations of GSDs from a number of specific sites. The manual emphasizes that the GSD value should be similar at all sites and site-specific values should not be needed unless there are great differences in child behavior and lead biokinetics among different sites." The Guidance Manual specifically states, "We must discourage the user from changing the GSD value by use of empirical site-specific data from a blood lead study." The manual points out that site-specific studies may be subject to subtle sampling biases and changes in child behavior in response to the study (Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children, US EPA, Feb 1994; and Technical Support Document: Parameters and Equations Used in the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children (v 0.99d), US EPA, Dec 1994).

EPA's IEUBK FAQs, which is published by EPA's Technical Review Workgroup for Lead, has this to say about changing the default GSD:

> "In general, the TRW does not recommend that site-specific estimates of the GSD be attempted. This parameter is particularly difficult to evaluate at a site, as it is demanding with regard to the amount and quality of the data and the potential complications in the analysis. Unless there are substantial differences in child behavior and lead biokinetics at your site, the default GSD should be used (since it is based on national averages). Thus, site-specific GSD values should not be needed. In particular, the TRW recommends that site-specific estimates of GSD not be substituted for the default value without detailed, scientifically defensible studies documenting site-specific differences in child behavior or lead biokinetics." (http://www.epa.gov/superfund/programs/lead/ieubkfaq.htm)

In a 1998 article by several EPA scientists, the authors review the basis for the GSD. The authors point out that the GSD of 1.6 is based on studies in children who live in Utah, Montana, and Baltimore and that the default GSD of 1.6 is likely to underestimate the true GSD because the GSD is based on a median value (White, PD et al., EHP 106, Supplement 6: 1513-1530, 1998).

EPA's guidance on using GSD limits its use to relatively small neighborhoods. Among other criteria, the manual points out that small neighborhoods consist of approximately 400 households and 100 children. The intent of this criteria is that smaller geographic areas are likely to have more uniform lead levels in a child's environment and therefore the default GSD of 1.6 is more likely to be accurate.

As noted in EPA's baseline risk assessment for the VBI70 site, the GSD for blood lead distribution has a significant effect on the predicted percent of children with blood lead levels above 10 μg/dL. It is important to realize that lowering the GSD to 1.2 will raise the clean-up level for lead and thus lower the number of properties that qualify for clean up. It should be noted that EPA's baseline risk assessment for the VBI70 site provides no data to support using a lower GSD, and changing the value arbitrarily (or with limited data) seems contradictory to EPA policy.

Community Health Program

The proposed plan makes the following statement: "Children who live in VBI70 will be further protected by a community health program with the following components... health education to raise overall community awareness about soil pica behavior and childhood exposure to lead from all sources."

Based on the current proposal, EPA is planning to use the community health education program in lieu of preventing future exposure by removing contaminated soil. ATSDR does not believe that the proposed soil clean-up levels are protective of public health; therefore, the agency does not think that the community health program is an appropriate use of medical testing and health education. We are concerned that using a medical testing and health education program as a substitute for appropriate soil clean-up levels will have limited value and will not protect public health in the long term.

To be effective, community health education must approach public health problems at multiple levels. (K. Glanz and B. Rimer, Theory at a Glance: A Guide for Health Promotion Practice, US DHHS, NIH, 1998)

Contemporary health promotion includes not only educational activities but also;

1. Developing advocacy groups to promote better health practices in a community,
2. Changing local policy that support educational activities,
3. Developing economic support for local communities,
4. Developing engineering controls to reduce pollution, and
5. Developing a comprehensive program to address a problem at multiple levels.

Similar health education programs have been implemented at other Superfund sites throughout the country. These programs, such as the one in Ruston North Tacoma, have encountered problems such as difficulties with evaluating their effectiveness and other issues which make it difficult to document the long-term usefulness of such programs. ATSDR suggests that EPA contact EPA and state staff from other regions who have worked with these programs to find out how effective the programs are before making a final decision about a community health program at the VBI70 site. It is important to note that at a minimum, community health education programs require adequate funding and staff to be effective.

Long-term Effectiveness of A Community Health Program

The proposed plan makes the following statement: "...EPA and CDPHE believe the Preferred Alternative would be protective of human health, would meet all Federal and State standards required by environmental laws, would be effective in the long term, and would be able to be implemented in the VBI70 community... "

Based on information from similar programs, and experience with the VBI70 community, ATSDR has concerns regarding the long-term effectiveness of the proposed community health program. Similar programs, such as, the Community Protection Measures Program in Ruston North Tacoma, Washington, have been in existence for several years. ATSDR suggests that EPA Region VIII gather information about the effectiveness of this program to determine if a program could be effective for the VBI70 site.

For example, the Ruston North Tacoma program encountered several unforseen obstacles while developing and implementing activities in that community. Some of the same obstacles could develop at the VBI70 site. For example, the area is a mix of rental and owner-occupied properties. As with any neighborhood, a certain percentage of owner-occupied homes will be bought and sold. Therefore, notification of future property owners will present a problem that could affect the long-term effectiveness of the proposed health education program. The most efficient method for notifying new property owners would include deed notices or some other documentation on the property deed that would alert new property owners of the health precautions that are in place for the area. However, such actions could adversely effect property values in the VBI70 area and could prevent some residents from selling or buying homes.

Community Involvement

It is important to realize that for a community health program to be successful, collaborative discussions need to take place with community representatives and local, state, and federal governmental and non-governmental agencies. For these discussions to be successful, the participants need to be treated as equal partners in decision making. ATSDR suggests that EPA avoid the standard approach of an agency developing a design followed by a comment period. Instead, ATSDR proposes that the participants develop the design jointly through group discussion and consensus building on the design components. Once the design components are agreed upon by the participants, a draft protocol is then appropriate.

Biological Monitoring

The proposed plan makes the following statement, "... a testing program to measure levels of lead in children's blood and levels of arsenic in children's urine to find out the level of actual soil pica exposure..."

In the past, both EPA and the State of Colorado have offered urine arsenic and blood lead testing to residents in the VBI70 communities with very limited response. This is similar to another site in Region X that offered long-term testing of children for urine arsenic, and the number of children who participated in the testing was very low. The low participation rate in these

programs could be for several reasons. For example, people may not want their children tested because:

1. They are afraid of the results,
2. They might be influenced by their doctor's advice to not be tested,
3. They have difficulty in scheduling an appointment,
4. They cannot pay for the test.

Based on the poor participation rates in the past at the VBI70 site and the continued trust issues that exist between the community and some government agencies, ATSDR questions whether a long-term testing program could achieve higher participation rates and whether the program could in fact identify children with exposure to arsenic or lead.

Similar to developing a community health program, the success of a biological testing program is dependent upon the community being involved in the discussions and the development of the program. Past experience at the VBI70 site and other sites have shown that government agencies alone setting up a testing program will not be successful. ATSDR suggests that EPA work with community representatives as equal partners in developing and implementing the testing program.

Alternative #6

ATSDR proposes an alternative #6 that incorporates the following points:

1. Developing lower clean-up levels for arsenic and lead at the VBI70 site,
2. Involving the community representatives as equal partners at every step,
3. Evaluating and reviewing similar programs at other hazardous waste sites, and
4. Developing and implementing a community health program that will be in place until clean-up is finished.

ATSDR suggests that EPA engage community representatives and staff members from other agencies to discuss and jointly determine the most appropriate soil clean-up levels for the VBI70 site. It is important that community representatives be treated as equal partners in developing and implementing all components of the community health program. By doing this, the community health program becomes a complement to the environmental engineering controls that will eventually reduce exposure to arsenic and lead in soil to safe levels.